

## **REMARKS**

Claims 1, 4-15, and 17-32 are pending in the case. Claims 1, 4, 23 and 24 are being examined and have been rejected.

### **Drawings**

Applicants have submitted a new set of formal drawings accompanied by a letter to the Official Draftsperson.

### **Rejection under 37 U.S.C. §112**

Claims 1 and 23 were rejected under section 112, paragraph 1, as not being fully enabled by the specification. It was contended that these claims lack support for variations in protein structure as having the requisite properties of a vaccine as based on the disclosure in the Figures and would have to be supported by data for 95%, 96%, etc., identity in order to be patentable.

In response, Applicants have amended claims 1 and 23. Amended claim 1 now recites a composition comprising a polypeptide at least 95% identical to SEQ ID NO: 6 (which is supported in the application at page 13, lines 1-5 and 24-28). Amended claim 23 now recites an isolated polypeptide at least 95% identical to SEQ ID NO: 6 (this claim is supported at page 13, lines 1-5, of the application).

Amended claim 4 is now an independent claim and recites a vaccine comprising a polypeptide with the amino acid sequence of SEQ ID NO: 6.

The claims were also rejected on grounds that new matter was added by

amendment adding the language "95% identical." Applicant respectfully directs the Examiner's attention to the application at page 13, lines 1-5 and 24-28. Applicant strongly disagrees with any assertion that new matter has been added. Two grounds were urged for this in the office action: firstly, that the insertion of "at least 95% identical" meant that 96%, 97%, etc., must be supported in the application. This is simply not the law. If it were, no one could ever cite "at least" a % identity in a claim. Thus, one would have to have data supporting the hundreds of different possibilities, such as 95.01%, 95.02%, 95.03%, etc., and that is not feasible. In fact, an Applicant need only provide a few representative examples, after which it is the responsibility of the Examiner to present evidence that this is not sufficient.

In addition, argument was made as to the use of the term "immunocompetent" in the claims as being an example of new matter. This assertion is ostensibly based on the notion that this term was not specifically used in the specification. While that may be true, the term immunocompetent simply means that the animal has an immune system capable of mounting an immunological response. Any animal that produces antibodies is therefor immunocompetent and no more was intended. Because the animals used in the examples presented in the application did produce antibodies (they would have been useless as experimental animals otherwise) they were certainly describable as immunocompetent regardless of the specific use of that term.

The term "new matter" refers to introduction of material in support of a claim where the material was not previously present in the application. Since it is clear, and would be so understood by those skilled in the art, that the animals used in examples of the application were capable of producing an immunological response, use of the term "immunocompetent" to describe them merely summarizes their characteristics as made clear by the results of the experiments and in no way rises to the level of "new matter." It is well settled law that an inherent property of a disclosed embodiment can be claimed. [See: *Kennecott Corp. v. Kyocera International Inc.*, 5 USPQ 2d 1194, at 1197, column 2, where the court re-affirms that a patent applicant who discloses an embodiment having

an inherent function necessarily discloses that function even though the Applicant says nothing concerning it – copy previously submitted]

In the interests of clarity, Applicants have amended claims 1 and 23 to delete the term "immunocompetent" as well as reference to the production of "protective antibodies." Applicants believe that this should overcome the ground of rejection. Claim 23 now recites that the polypeptide elicits production of antibodies against *S. pneumoniae*.

Claims 23 and 24 were also rejected as not being supported in the specification by data showing the ability of polypeptide of varying percentage identities to SEQ ID NO: 6 to elicit production of antibodies that protect against streptococcal infection and for use of the term "immunocompetent animal."

In response, Applicants have amended claims 23 and 24 to recite simply an isolated polypeptide.

Claims 1, 4, 23 and 24 were also rejected as being indefinite (under 35 U.S.C. 112, second paragraph) for use of the phrase "identical to" without reciting that SEQ ID NO: 6 is an amino acid sequence. In the interests of clarity, Applicants have amended claims 1 and 23 to recite that SEQ ID NO: 6 is an amino acid sequence. However, Applicants note that this is clear from looking at the sequence. In view of these amendments, Applicants believe that this ground of rejection has been overcome.

Applicants also include herewith a Request for Continued Examination along with the required fee for a large entity. Because Applicants previously filed a Notice of Appeal, the time to respond was extended to April 28 for the Appeal Brief. Thus, the present response is timely and no extension fees are believed due.

The Commissioner is authorized to charge payment of any additional filing fees required under 37 CFR 1.16 associated with this communication or credit any

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 4/28/03  
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Respectfully submitted,



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